

**Summary of Selected Technical Details and Reported Ethical Factors
for a Sample of Experimental Studies with Human Subjects**

12/7/98

Study Year	Selected Technical Details						Ethical Factors Reported ¹					
	Exp Route	No and Sex of subjects	Doses	Duration	Pre-exp ChE	Statistical measures ²	Vol subj	Inf Con	IRB	D of H	HHS CR	EPA CR
?	oral	7 ♂ 4 ♂ 2 ♂ 1 ♂	1 dose	acute 30 d 60 d 120 d	Y	none reported	Y	-	-	-	-	-
66	oral	3 ♂/dose	0 dose 1 dose 2	6 wks	Y	t-tests for group means	Y	-	-	-	-	-
70	oral	4♂ 6♂	controls 4 doses in ascending series	21 d for I-3; 3 d for 4	Y	ANOVA and t-tests	Y	-	-	-	-	-
71	oral, neat	4 ♂/dose	3 doses	acute	Y	F-tests; comparisons between doses as % of -1 hr value, % of max pre-dose value (-18 hrs)	Y	-	-	-	-	-
71	oral	1 ♂ >1? ♂	1 dose 1 dose	acute acute	Y	none reported	Y	-	-	-	-	-
72	oral, in tablets	4♂/dose	0 dose 1 dose 2 dose 3	49d 27d 22d 9d	Y	Repeated measures ANOVA; day x dose interaction	Y	-	-	-	-	-
72	oral	5 ♂ / 5 ♀	1 dose	28 d	Y	none reported	Y	Y	-	-	-	-
74	oral	5 ♂	1 dose	28 d	Y	none reported	Y	-	-	-	-	-
76	oral	3 ♂ 4 ♀	1 dose	56 d	Y	none reported	Y	Y	-	-	-	-
76	oral	2-4 ♂/dose	3 doses	acute	Y	none reported	Y	Y	Y	-	-	-
77	dermal	2 ♂/dose	0 doses 1-7 dose 8	acute 3 d	Y	none reported	Y	Y	Y	-	-	-

Study Year	Selected Technical Details						Ethical Factors Reported ¹					
	Exp Route	No and Sex of subjects	Doses	Duration	Pre-exp ChE	Statistical measures ²	Vol subj	Inf Con	IRB	D of H	HHS CR	EPA CR
77	oral	10 ♂ / 10 ♀	1 dose; each S had placebo	16 d	Y	Wilcoxon sum rank test for comparing groups	Y	Y	-	-	-	-
79	oral	4 ♂ 4♂/dose	controls 2 doses	25-28 d	Y	repeated measures ANOVA; t-tests, other <i>post-hoc</i> tests	Y	Y	Y	-	-	-
82	oral dermal	6♂ 5♂	1 dose 1 dose	acute acute	Y	none reported	Y	-	-	-	-	-
90	oral	20 patients with Alzheimer's disease	5 sequential doses: dose 1 dose 2 dose 3 dose 4 dose 5	weekly acute acute twice twice 4-12	Y	none reported for ChE measures	-	Y	-	-	-	-
92	oral, in juice	4-6 ♂/dose 4 ♀/dose	4 doses 3 doses placebo given to dosed Ss	acute	Y	Repeated measures ANOVAs <i>post-hoc</i> contrasts	Y	Y	Y	Y	-	-
97	oral	6 ♂	1 dose	acute	Y	Paired t-test for groups; individual differences from pre-exposure; Goode permutation test	Y	Y	Y	Y	-	-
97	oral	6 ♂	1 dose, placebo, 2 nd acute dose, then subacute dosing; sequentially in each S	acute 12-15 d	Y	Paired t-test for groups; individual differences from pre-exposure; Goode permutation test	Y	Y	Y	Y	-	-

¹ "Y" indicates that the study report asserted that, in order, subjects were volunteers, informed consent was obtained, an Institutional Review Board oversaw the study, it complied with the Declaration of Helsinki, it complied with the HHS Common Rule, or it complied with the EPA Common Rule.

² Statistical analyses described apply to the cholinesterase data, which in most cases were the only data statistically analyzed.